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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,129	YOUNG ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/04; 7/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed October 6, 2006 in response to the Office Action of August 7, 2006 is acknowledged and has been entered.

Applicant's election with traverse of Group II, claims 1-8, 15 and 16 and the species antibody alone, antibody mediates antibody dependent cellular cytotoxicity, and breast tumor is acknowledged.

Applicants argue that the non-conjugated and conjugated antibodies are not independent inventions since conjugation is a further limitation on the antibody. Applicants argue conjugated antibodies comprise the same antibody as the non- conjugated antibodies (shared structure), which work by binding an antigenic moiety (shared mode of operation) to treat a cancerous disease (shared effects). Applicants argue a search for a non-conjugated antibody and the conjugated antibody clearly overlaps.

Upon review and reconsideration, the requirement for the election of species between an antibody alone and an antibody conjugated to a cytotoxic moiety will be withdrawn because it would be obvious to conjugate an antibody to a cytotoxic moiety for increased efficacy in the treatment of a human tumor.

Applicant argues that complement mediated antibody cytotoxicity and antibody mediated cellular cytotoxicity are not independent inventions because each type places a further limitation on the antibody by defining how the cytotoxicity of the antibody is achieved. Both types have the same effect, i.e. cytotoxicity. Applicant argues that search of the prior art should center on the specific monoclonal antibody. Applicant argues that, for example, one of skill in the art would not attempt to search each of the types of cytotoxicity mediated without connecting the search to

the antibody since a search of both types alone would result with thousands of hits related to many different antibodies. Applicant argues that accordingly, the search for both types of cytotoxicity is considered overlapping and thus, the election of species is improper.

Applicants' argument has been considered, but has not been found persuasive because different antibody isotypes differ in their ability to stimulate complement-mediated cytotoxicity or cellular mediated cytotoxicity. Thus, the antibodies that effectively mediate each form of cytotoxicity are distinct and thus the literature search is not coextensive. Thus different searches and issues are involved in the examination of each species.

Applicants argue that each type of tumor tissue (breast or ovarian) is not an independent or distinct invention. Applicants argue that the tumor tissue is not a step of the described methods. Applicants argue that cells obtained from both of these tumor tissues were used with the same claimed methods. Applicants argue that these methods operate the same way in both of the tissues, i.e. the antibody binds the same antigenic moiety in both of the tissues. Applicants argue that the instant inventors found that human tumor cells obtained from breast and ovarian tissues expressed an antigenic moiety which bound the described monoclonal antibody encoded by the clone deposited with the ATCC as PTA-5643 and thus were able to be treated successfully with the described monoclonal antibody. Applicants argue that a search of the prior art regarding tumor tissues should center on the specific monoclonal antibody. Applicants argue that when one of skill in the art searches the antibody one would expect to retrieve information about the antibody including any tissues with which the antibody is involved.

Applicant's argument has been considered, and has been found persuasive in part. Claim 1 is generic to any tumor type including breast and ovarian tumors as contemplated in the

specification and claimed. Furthermore, although the method may operate the same way for both tissues, the effect of a given therapy for different tumor types can vary significantly. Thus different searches and issues are involved in the examination of each species.

However, in view of the effectiveness of the antibody on breast and ovarian tumors and to advance prosecution, the requirement for an election of species between breast and ovarian tumors will be withdrawn.

The issues remain the same for the reasons set forth previously and above, thus the restriction requirement is deemed to be proper and is therefore made FINAL.

3. Claims 1-3, 5-8, 15, and 16 are currently pending and under consideration.

Specification

4. The disclosure is objected to because of the following informalities: A word appears to be missing after the word enhance on p. 9, line 22.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 5-8, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5-8, 15, and 16 are indefinite because claim 1 recites the phrase "identifying characteristics". The claims are indefinite because the specification provides no definition of "identifying characteristics". Thus it is not possible to determine if the identifying characteristics of the claimed product used in the claimed method are drawn to the product's characteristics as a monoclonal antibody, as a protein, as a binder to a particular antigen, or as a binder to a cancer cell. Given the above, the metes and bounds of the subject matter claimed cannot be determined and neither the specification nor the claims as originally filed particularly points out or distinctly claims the subject matter which applicant regards as the invention.

6. Claim 8 is indefinite because it recites the phrase a "chimerized antibody". The exact meaning of the word chimera is not known. The term chimera is generic to a class of antibodies which are products of genetic shuffling of antibody domains and other active proteins. The term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including but not limited to CDR grafted antibodies. Thus the metes and bounds of the claim protection sought cannot be determined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 5-8, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are drawn to a method of extending survival by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the **identifying characteristics** of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby survival is extended (PTA-5643 is also denoted in the specification as 11BD-2E11-2, herein referred to as PTA-5643 for simplicity), see para. bridging pp. 18-19.

The specification teaches that the monoclonal antibody PTA-5643 was obtained following immunization of mice with cells from a patient's breast tumor biopsy, p. 8, lines 2-4. Furthermore, the specification teaches that the PTA-5643 antigen is expressed on the cell surface

of a broad range of human cell lines from different tissue origins (p. 8, lines 18-19). Neither. the antigen to which PTA-5643 binds was not taught in the specification or what the identifying characteristics of PTA-5643 are.

One cannot extrapolate the teaching of the specification to the scope of the claims because there is insufficient guidance and direction as to how to make and use antibodies which have the identifying characteristics of monoclonal antibody PTA-5643 because they are being defined by an antibody which binds to an unknown antigen.

As drawn to antibodies being defined by unknown antigens, the courts have found that definition of an antibody by binding to an unknown is not enabling. In particular, the court teaches as follows: "Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to

another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen". *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 1/20/2004).

To reiterate, applicant is claiming antibodies against an unknown and since an antibody is defined by its antigen binding capability, claims drawn to antibodies that have the same characteristics as antibodies that bind to unknown antigens are not enabled. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predictably make or use the broadly claimed antibodies with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

7. If applicant were able to overcome the rejection under 35 U.S.C. 112, first paragraph, claims 1-3, 5-8, 15 and 16 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of **extending survival** by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics which is encoded by a clone deposited with the ATCC as accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby **survival is extended**, does not reasonably

provide enablement for a method of extending survival and/or **delaying disease progression** by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby **disease progression is delayed** and/or survival is extended. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are drawn to a method of extending survival and/or delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal

antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended.

This means that one can extend survival and/or **delay disease progression** by treating a human tumor in a mammal with a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the accession number PTA-5643.

The specification teaches that PTA-5643 prevented tumor growth and reduced tumor burden in a preventative in vivo model of human breast cancer. The specification teaches that monitoring of the mice continued past 280 days post-treatment with PTA-5643 and 40 % of the PTA-5643 treatment group was still alive at over 7.5 months post-implantation. The specification teaches that, conversely, the isotype control group had 100 percent mortality after 6.5 months post-treatment. The specification teaches that at day 51 (soon after last treatment), the mean tumor volume in the PTA-5643 treated group was 20% of the isotype control ($p=0.0098$), see p. 9 lines 16-21, Example 1, and Fig. 1 and 2. The specification teaches that PTA-5643 increased survival and decreased tumor burden in a well-established model of human breast cancer, see p. 16, lines 13-14.

The specification teaches that in the OVCAR-3 ovarian cancer xenograft model, increasing body weight can be used as a surrogate indicator of disease progression since this reflects the accumulation of ascites from increased tumor burden. The specification teaches that at day 80 post-implantation (16 days after the end of treatment), PTA-5643 administration prevented body weight gain by 12.4 percent ($p=0.015$) compared to the buffer control group. Mice were monitored post-treatment for survival. The specification teaches that by day 87, the buffer control group had reached 90 percent mortality while the PTA-5643 treated group still had

80 percent survival. The PTA-5643 treated group did not reach 90 percent mortality until day 125. The specification teaches that the PTA-5643 antibody treatment reduced tumor burden, delayed disease progression and enhanced survival in comparison to a buffer control antibody in a well-recognized model of human ovarian cancer, see Example 2, p. 17 lines 8-17, and Fig. 3 and 4.

One cannot extrapolate the teaching of the specification to the scope of the claims because the measurement of body weight is not a predictable measurement of cancerous disease progression.

In particular, those of skill in the art for example, Tannock and Hill, recognize that cancer progression is defined as the tendency of tumors to become more malignant as they grow, p. 399 (Tannock, I. F. and Hill, H. P., The Basic Science of Oncology, 1992). However nothing in the specification indicates that the treatment delays the progression to metastases for any tumor. Tannock and Hill teach that malignancy is the essential property of cancer cells that is demonstrated by their ability to proliferate indefinitely, to invade surrounding tissue, and to metastasize to other organs, p. 399. Additionally, Hill (The Basic Science of Oncology, Tannock, I. F. and Hill, H. P. eds. 1992, Ch. 11, p.178-195) teaches that the metastatic cell must establish new growth at its new location in the organism, see Ch. 11, Section 11.2.6. Thus, progressed, metastatic tumor cells must proceed through multiple steps to affect the host by establishment and growth of cells at a distal site. Hill teaches assays which measure metastasis by enumerating the ability of tumor cells to establish new growth at distal sites through direct or indirect counting of the number of ectopic growths, see Section 11.3.1 and Figure 11.8.

Additionally, Hu et al. (Clinical Cancer Research, 2000, 6:880-886) teach that the assessment of body weight **and** (emphasis added) abdominal circumference may be a practical, but imprecise, way to assess the increasing volume of ascites **and** (emphasis added) tumor burden in vivo when using the OVCAR-3 tumor model, see p. 885, left column and Fig. 3.

Thus it is clear, given the above, that measurement of body weight alone is an insufficient measure of tumor progression, although the specification teaches increasing body weight can be used as a surrogate indicator of disease progression since this reflects the accumulation of ascites from increased tumor burden (see above), because the increased tumor burden may be a result of increased tumor growth and not necessarily increased ascites alone (the marker for disease progression).

Thus neither the specification nor the art of record teaches that the administration of PTA-5643, in fact, delays metastasis in any tumor type. Given the above it is not clear that treatment with PTA-5643 could effectively delay progression in any tumor as understood by those of skill in the art. Thus, undue experimentation would be required to demonstrate the PTA-5643 delays tumor progression in any tumor type.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly state in the

specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

8. If applicant were able to overcome the rejection under 35 U.S.C. 112, first paragraph, claims 1-3, 5-8, 15 and 16 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of extending survival and/or delaying disease progression by treating a **human breast or ovarian tumor** in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics which is encoded by a clone deposited with the ATCC as accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, does not reasonably provide enablement for a method of extending survival and/or delaying disease progression by treating **a** human

tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are drawn to a method of extending survival and/or delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal

antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended.

This means that one can extend survival and/or delay disease progression by treating **any** tumor in a mammal with a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the accession number PTA-5643.

The specification teaches that the monoclonal antibody PTA-5643 was obtained following immunization of mice with cells from a patient's breast tumor biopsy, p. 8, lines 2-4. Additionally, the specification teaches that the PTA-5643 antigen is expressed on the cell surface of a broad range of human cell lines from different tissue origins (p. 8, lines 18-19). However, the specification teaches that the breast cancer cell line MCF-7 and ovarian cancer cell line OVCAR-3 were the only two cancer cell lines tested that were susceptible to the cytotoxic effects of PTA-5643, see p.8, lines 19-21.

The specification teaches that PTA-5643 prevented tumor growth and reduced tumor burden in a preventative in vivo model of human breast cancer. The specification teaches that monitoring of the mice continued past 280 days post-treatment with PTA-5643 and 40 % of the PTA-5643 treatment group was still alive at over 7.5 months post-implantation. The specification teaches that, conversely, the isotype control group had 100 percent mortality after 6.5 months post-treatment. The specification teaches that at day 51 (soon after last treatment), the mean tumor volume in the PTA-5643 treated group was 20% of the isotype control ($p=0.0098$), see p. 9 lines 16-21, Example 1, and Fig. 1 and 2. The specification teaches that PTA-5643 increased survival and decreased tumor burden in a well-established model of human breast cancer, see p. 16, lines 13-14.

The specification teaches that in the OVCAR-3 ovarian cancer xenograft model, increasing body weight can be used as a surrogate indicator of disease progression since this reflects the accumulation of ascites from increased tumor burden. The specification teaches that at day 80 post-implantation (16 days after the end of treatment), PTA-5643 administration prevented body weight gain by 12.4 percent ($p=0.015$) compared to the buffer control group. Mice were monitored post-treatment for survival. The specification teaches that by day 87, the buffer control group had reached 90 percent mortality while the PTA-5643 treated group still had 80 percent survival. The PTA-5643 treated group did not reach 90 percent mortality until day 125. The specification teaches that the PTA-5643 antibody treatment reduced tumor burden, delayed disease progression and enhanced survival in comparison to a buffer control antibody in a well-recognized model of human ovarian cancer, see Example 2, p. 17 lines 8-17, and Fig. 3 and 4.

One cannot extrapolate the teaching of the specification to the scope of the claims because the art teaches that PTA-5643 is selective for breast and ovarian cancer cells in its cytotoxic activity and the heterogeneity of cancers and their response to treatment is well known in the art.

1) In particular, as drawn to the heterogeneity of cancers, Young et al. (US Pat. No. 7,009,040 B2, 2003) teach that PTA-5643 (11BD-2E11-2) was specifically cytotoxic in breast and ovarian cancer cells, see column10 and Table 2. Furthermore, Young et al. teach that the antibodies were selective in their activity since not all cancer cell types were susceptible, see columns 10 and 11.

Furthermore, the art teaches that cancers comprise a broad group of malignant neoplasms divided into two categories, carcinoma and sarcoma. The carcinomas originate in epithelial tissues while sarcomas develop from connective tissues, see Taber's Cyclopedic Medical Dictionary (1985, F.A. Davis Company, Philadelphia, p. 274). Given that not all cancers originate from the same tissue types, it is expected and known that cancers originate from different tissue types have different structures as well as etiologies and would present differently. Thus, it would not be predictably expected that a nexus, for example drawn to a connection between PTA-5643 and extending survival, would be established between two cancer types that arose from different tissue types. Further, it is well known that even two carcinomas that present on the same organ have significant differences in etiology and genetic constitution. For example, Busken, C et al, (Digestive Disease Week Abstracts and Itinerary Planner, 2003, abstract No:850), teach that there is a difference in COX-2 expression with respect to intensity, homogeneity, localization and prognostic significance between adenocarcinoma of the cardia and distal esophagus, suggesting that these two cancers have different etiology and genetic constitution (last five lines of the abstract). Furthermore Krontiris and Capizzi (Internal Medicine, 4th Edition, Editor-in-chief Jay Stein, Elsevier Science, 1994 Chapters 71-72, pages 699-729) teach that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocols. Chemotherapeutic agents are frequently useful against a specific type of neoplasm and especially with the unpredictability of the art there are no drugs broadly effective against all forms of cancer, see Carter, S. K. et al. Chemotherapy of Cancer; Second edition; John Wiley & Sons: New York, 1981; appendix C. Given the above, it is clear that it is not possible to predictably extrapolate a correlation between

PTA-5643 and extending survival in any tumor type other than breast and ovarian cancer, based on the information in the specification and known in the art without undue experimentation.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly state in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

9. If applicant were able to overcome the above rejections set forth above under 35 U.S.C. 112, first paragraph, claims 1-3, 5, 6, 8, 15, and 16 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of extending survival and/or delaying disease progression wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, wherein said antibody is a **humanized** antibody, does not reasonably provide while being enabling for a method of extending survival and delaying disease progression wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, wherein said antibody is a **murine** antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims read on treating a human tumor in a mammal with a mouse monoclonal antibody PTA-5643. This means the claims read on, and the specification contemplates, the treatment of cancer in humans with antibodies produced in a mouse.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

> the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The specification teaches that the monoclonal antibody PTA-5643 was obtained following immunization of mice with cells from a patient's breast tumor biopsy, p. 8, lines 2-4.

One cannot extrapolate the teachings of the specification to the scope of the claims because Winter et al (TIPS, 1993, 14:139-143) specifically teach that a major problem with the use of murine monoclonal antibodies in the treatment of human subjects is the development of human antimouse antibodies (HAMA) that can inactivate the injected antibodies. Thus, it would be expected that the injection of cross species antibody would result in anti-other species antibodies and/or cytotoxic T cells against the injected antibody. Further, Baselga et al (J. Clin. Oncol, 1996, 14:737-744) specifically teach that murine antibodies are limited clinically because they are immunogenic.

Given the above, it is clear that it is not possible to predict that a mouse monoclonal antibody PTA-5643 would successfully treat a human tumor in a human as contemplated in the specification. Thus it would require undue experimentation to practice the broadly claimed invention.

10. If applicant were able to overcome the rejection under 35 U.S.C. 112, first paragraph, claim 5 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity, wherein the monoclonal antibody which has the identifying characteristics of a PTA-5643 is of the murine immunoglobulin subclass IgG2A or IgG3 or humanized with human immunoglobulin subclass IgG1 or IgG3, does not reasonably provide enablement for the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 5 is drawn to the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity.

This means that the antibody must be able to mediate antibody dependent cellular cytotoxicity for the method of the claimed invention.

The specification teaches that it is generally thought that cancer cell killing by naked antibodies are mediated either through antibody-dependent cell-mediated cytotoxicity or complement-dependent cytotoxicity. The specification teaches that murine antibodies of the IgG2a and IgG3 isotype are effective at recruiting cytotoxic cells that have Fc receptors which will lead to cell killing by monocytes, macrophages, granulocytes and certain lymphocytes. Human antibodies of both the IgGl and IgG3 isotype mediate antibody-dependent cell-mediated cytotoxicity, p. 11, lines 6-15.

One cannot extrapolate the teachings of the specification to the scope of the claim because no nexus has been established between a monoclonal antibody with the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 and antibody dependent cellular cytotoxicity and because it is well known in the art that not all antibody subclasses mediate antibody dependent cellular cytotoxicity.

In particular, Dillman (Annals of Internal Medicine, 1989 111:592-603) teaches that different classes and subclasses of mouse immunoglobulins have different affinities for human effector cells that mediate antibody dependent cellular cytotoxicity because of differences in the Fc portion of the heavy chain, see p. 593, left column. Dillman teaches that the best results for antibody-dependent cell mediated cytotoxicity for murine antibodies are obtained with IgG2A and IgG3 and for mouse-human chimeric antibodies better results are confined to human IgG1 and IgG3 monoclonal antibodies.

Thus, in view of the above, one would not expect and therefore could not predict that any class of antibody, other than the cited IgG antibody isotypes, would function as claimed with a reasonable expectation of success. Thus undue experimentation would be required to determine if an antibody with the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 could mediate antibody dependent cellular cytotoxicity.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA

1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly state in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

11. Claims 1-3, 5-8, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5-8, 15, and 16 are broadly drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof, comprising administering a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643. It is noted that the antigen to which PTA-5643 binds has not been characterized other than to note that the antibody binds to an antigen in a number of cell lines, thus, no identifying characteristics, other than cell line binding, of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 are known. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have

> previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a peptide antigen product itself logically cannot adequately describe an antibody to that antigen product.

Thus, the instant specification may provide an adequate written description of the antibody with identifying characteristics of PTA-5643 useful for extending survival and/or delaying disease progression, per Lilly by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus". Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe monoclonal antibodies with identifying characteristics useful for extending survival and/or delaying disease progression in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of identifying characteristics of the claimed antibody other than its presence at the cell surface of various cell lines, nor does the specification provide any partial structure of such identifying characteristics, nor any physical or chemical characteristics of the said identifying characteristics nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses that the PTA-5643 antigen is expressed on the cell surface of a broad range of human cell lines from different tissue origins (p. 8, lines 18-19), this does not provide a description of the identifying characteristics of the claimed antibody.

The specification also fails to describe the identifying characteristics by the test set out in Lilly. Therefore, it necessarily fails to describe a "representative number" of such species. In

addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the claimed identifying characteristics of the monoclonal antibody PTA-5643 that are required to practice the claimed invention. Since the specification fails to adequately describe the identifying characteristics of the claimed antibodies useful for extending survival and delaying disease progression by treating a human tumor in a mammal, it also fails to adequately describe the claimed method.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 7, 8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cobleigh et al. (Journal of Clinical Oncology, 1999, 17:2639-2648) as evidenced by Baselga and Albanell (Annals of Oncology 12, 2001 (suppl. 1): S35-S41).

Given the indefinite claim language drawn to "identifying characteristics" as set forth above, it is assumed for examination purposes that the identifying characteristics of the PTA-5643 includes a monoclonal antibody which binds breast tumor tissue antigens.

The claims are drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof, comprising

administering a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in a n amount effect to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended (Claim 1), wherein said antibody is a murine antibody (Claim 6), wherein said antibody is a humanized antibody (Claim 7), and the method of claim 1, wherein said tumor is a breast tumor (claim 15).

Cobleigh et al. teach treating metastatic breast cancer in women with a humanized, murine anti-HER2 monoclonal antibody (Trastuzumab) that delayed progression and increased survival (see Materials and Methods-Tumor Response, p.2640, right column; p. 2641, left column to p. 2642 left and right column; and Fig. 1), wherein the monoclonal antibody binds to breast cancer cells and thus shares identifying characteristics with PTA-5643. Baselga and Albanell teach that Trastuzumab induces antibody-dependent cellular cyototoxicity against breast cancer cells, see p. 38, left column.

All of the limitations of the claims are met.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobleigh et al. (Journal of Clinical Oncology, 1999, 17:2639-2648), in view of Dillman (Annals of Internal Medicine, 1989; 111:592-603),.

The claims are drawn to the method of claim 1wherein said antibody is conjugated to a cytotoxic moiety (Claim 2) and wherein said cytotoxic moiety is a radioactive isotope (Claim 3).

Cobleigh et al. teach treating metastatic breast cancer in women with a humanized anti-HER2 monoclonal antibody that delayed progression and increased survival (see Materials and Methods-Tumor Response, p.2640, right column; p. 2641, left column to p. 2642 left and right column; and Fig. 1). Cobleigh et al. does not teach that the antibody conjugated to a cytotoxic moiety, wherein said cytotoxic moiety is a radioactive isotope.

Dillman teaches that due to the limited efficacy of monoclonal antibodies alone in clinical treatments, cytotoxic immunoconjugates are employed (p. 595, left column). Dillman also teaches that the radiolabeled immunoconjugates are the technically easiest to make (p. 595, right column).

Thus, the state of the art at the time the invention was made not only included the knowledge of treating human tumors in a mammal with a monoclonal, humanized antibody with the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 and that antibodies could easily be conjugated to radioactive cytotoxic moieties to successfully improve treatment. Thus one of ordinary skill in the art would have had motivation and a reasonable expectation of success in making and using the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and

useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 1 and 5-8 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33 and 37-40 of copending Application No. 10/949,846. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. Claims 1 and 5-8 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33and 37-40 of copending Application No. 10/810,744. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* , 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 5, and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 10 of copending Application No. 11/370,255.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to application number 11/370,255 which is drawn to a method of treating human breast and ovarian tumors susceptible to antibody induced cellular cytotoxicity in a mammal, wherein said human breast and prostate tumors express an antigen which specifically binds to the isolated monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 or a cellular cytotoxicity inducing ligand thereof, comprising administering to said mammal a monoclonal antibody or cellular cytotoxicity inducing ligand in accordance with any one of claim 1 or 2 or 3, in an amount effective to induce cellular cytotoxicity and thereby reduce said mammal's tumor burden (Claim 6) and the method of claim 6 wherein said monoclonal antibody or ligand mediates antibody dependent cellular cytotoxicity (Claim 10)

Given that the claims of copending Application No. 11/370,255 are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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PJR

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PRIMARY EXAMINER